

REMARKS

Reconsideration of this application, as amended, is requested.

Claims 3, 25 and 26 remain in the application. Claims 25 and 26 have been amended to define the invention more clearly. Claim 2 has been cancelled. Claims 5 and 27 are withdrawn in view of a restriction requirement.

The claims were rejected under 35 USC 102(b) as being anticipated by Anderson et al., U.S. Patent No. 5,800,526.

The Anderson et al. reference shows a stent/graft assembly where the end of the graft is telescoped over the end of the stent. The Anderson et al. reference has no suggestions of a stent/graft assembly where the first axial end of the tubular graft means is "fixedly connected to the second axial end of the stent means to achieving a substantially end-to-end connection without overlap." The applicant herein has determined that the difference between a telescoped overlapped connection (e.g. Anderson et al.) and an end-to-end connection is substantial. In this regard, the Examiner will appreciate that the stent of a stent/graft assembly has one of many commercially available structures (e.g. a Z-stent) that permits the stent to be collapsed for introduction into the blood vessel. Once properly positioned, the stent is expanded into engagement with the inner circumferential surface of the blood vessel. The Anderson et al. graft must be dimensioned to telescope over the end of the expanded stent for introduction into the blood vessel. Therefore, the Anderson et al. graft must collapse with the stent. However, the graft does not have the complex construction of the stent, and is collapsed due to the flexible nature of the Dacron (PET) or Gortex (E-PTFE) from which the graft is likely to be made. Thus, the graft must be folded or otherwise gathered into overlapping relationship with the collapsed stent, in much the manner of a pleated skirt. The overlapping of material on a pleated skirt does not add

significantly to the overall dimensions of the skirt. However, when employed in the much smaller environment of an endovascular stent/graft assembly the overlapping of the graft onto the stent and the pleating or other gathering of the graft onto the collapsed stent is very significant.

Surgeons who perform these types of operations refer to the "French size" of the graft, stent or introducer. The French size refers to the outer circumference of the stent or graft in millimeters. An overlapped stent/graft assembly, as shown in Anderson et al., would require an introducer of 20 or 22 French. In contrast, the claimed end-to-end connection of the stent and graft avoids the additional dimensions attributable to the telescoped overlap of Anderson and further avoids the additional dimensions attributable to pleating or other gathering the graft onto the collapsed stent. Hence, the claimed stent/graft assembly can be used with a 12 French introducer. These size, are shown below:



22 French



12 French

The difference between a 12 French introducer and 20 or 22 French introducer is tremendous in terms of the surgical and post-surgical implications. In this regard, the aneurysm is likely to occur in an artery and not a vein. Therefore, the endovascular stent/graft assembly must be introduced into an artery and not a vein. The typical site of introduction is the femoral artery, which is one of the larger arteries in the body. Arterial blood, unlike venous blood, is under tremendous pressure. Thus, an incision into an artery, such as the femoral artery, produces a very significant gushing and pulsating flow of blood. The incision into a major artery for a 20 or 22 French

introducer is likely to produce significant bleeding and requires a more complicated closure. In contrast, the opening for a 12 French introducer produces much less bleeding during surgery and the closure is sufficiently simple to permit the surgery to be performed on an outpatient basis. The incision for a 12 French introducer generally can be closed merely with pressure and a dressing, and without sutures. The incision for a 20 or 22 French introducer requires sutures and typically requires a stay in the hospital while the closure is monitored for proper healing. Thus, the claimed invention enables an otherwise complex surgical procedure to be reduced more to the nature of a dentist visit.

Additionally, the femoral arteries of most women are too narrow for the overlapping endovascular devices shown in Anderson et al. Thus, a woman with an aneurysm typically will require a direct surgical repair at the site of the aneurysm, and a much longer hospital stay. However, the substantially end-to-end connection with no overlap provided by the stent/graft assembly of the subject invention would enable women with an aneurysm to have the aneurysm repaired with an endovascular stent/graft assembly.

Anderson et al. has no suggestion of the structure defined by the amended claim nor the advantages enabled by the subject invention, as set forth above. Accordingly it is submitted that the invention defined by the amended claim is directed to patentable subject is solicited.

Respectfully submitted,



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